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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/189,543 | 11/10/1998 | MARK CHEE | A-66828-1/DJ | 5598 |

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EXAMINER

MARSCHER, ARDIN H

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| ART UNIT | PAPER NUMBER |
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1631

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/189,543

Applicant(s)

CHEE ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38,40-47,52-55,58-62 and 64-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38,40-47,52-55,58-62 and 64-68 is/are rejected.
- 7) ☒ Claim(s) 68 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. 8/20/04.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 8/23/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Upon reconsideration, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

NOT FURTHER LIMITING CLAIM

Claim 68 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 68 depends from claim 67 which limits the nucleic acid identifier binding ligands to being DNA. Claim 68 may be reasonably interpreted as broadening the nucleic acid identifier binding ligands to being single stranded nucleic acids which commonly include both RNA as well as DNA.

PRIOR ART

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 38 and 40-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel et al. (P/N 5,837,196).

Pinkel et al. has been previously described regarding disclosing the basic limitations of the instant invention such as high site densities of randomly distributed microspheres on a substrate such as a fiber optic bundle with bioactive binding ligands. Citations in Pinkel et al. were directed to column 7, lines 10-23; column 8, lines 39-56; and column 8, line 63, through column 9, line 2. Additionally, various bioactive binding entities are described in the reference in column 6, line 23, through column 7, line 9, as well as simultaneous detection of different analytes via different classes of binding partners in column 14, lines 36-42. The previous office action, mailed 8/11/04, indicated that a limitation as in now canceled claim 39 which limits the array composition over the previous form of claim 38, for example, regarding part c) now of claim 38 was not rejected over prior art. Regrettably, a reconsideration of Pinkel et al. reveals a multi-component detection sandwich on the fiber optic arrays described therein which is now deemed to motivate and suggest a specie of array composition which causes the withdrawal of that previous indication of allowable subject matter. It has been found that Pinkel et al. in column 15, lines 14-20, describes such a complex detection sandwich with various labels described in column 15, line 21, through column 16, line 20. In said column 15, lines 14-20, detection sandwich on the array surface, a first biological

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binding partner on the sensor surface is present which is the bioactive agent of instant claim 38. Secondly, this binding partner immobilizes the analyte which is then identified by yet a third entity described in the reference as a second binding partner which is labeled. The analyte is thus identified in this sandwich and qualifies as the different identifier binding ligand in embodiments wherein there is simultaneous detection of different analytes as noted above. The above described third entity is the at least one decoder binding ligand comprising a label as set forth in instant claim 38, part c). It is noted that instant claim 38, for example, does not require any analyte which is a separate entity from those cited as binding entity types in the claim.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the above described array compositions with particular species of analyte detection sandwich entities also as described above to practice the above listed instant invention as claimed in the above listed claims with a reasonable expectation of success.

Claims 38, 40-47, 52-55, 58-62, and 64-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel et al. (P/N 5,837,196); taken in view of Matthews et al. [Analytical Biochemistry, 169:1-25 (1988)].

The above Pinkel et al. description is directed to the basic invention as instantly claimed in claims 38 and 40-47 but therein is generic as to the type of identifier binding ligands practiced in the claims. Such generic ligands are described generically as binding partners in Pinkel et al. in column 15, lines 14-20, as also described in the above rejection explanation based on Pinkel et al. Instant claims 52, 54, and 55, limit

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the type of identifier binding ligands to nucleic acids wherein these claims also limit the bioactive agent bound onto solid support microspheres to being a protein. The detection sandwich description in Pinkel et al. reasonably suggests and motivates generic immobilized detection sandwiches of this type wherein the third entity is labeled for detection. Pinkel et al. does not describe the specific immobilized protein bioactive agent, nucleic acid identifier ligand, with a labeled decoder ligand sandwich.

Matthews et al. is a review publication directed to analyte detection via various practices utilizing DNA probes as summarized in the title. A variety of labels are listed, for example, on page 6, TABLE 2 with surrounding descriptions of a wide variety of labeling strategies. A variety of solid support substrate types for immobilization of probe complexes is listed on page 15, TABLE 7, including plastic, beads, microparticles, etc. On page 17, Figure 10, a sandwich detection complex is described wherein a protein is immobilized on the solid support, given therein as SA (streptavidin). A biotinylated nucleic acid identifier ligand is then attached thereto, and a labeled decoder ligand is further attached, shown generically labeled with a star symbol. This detection complex is that as instantly claimed with a protein bioactive (SA) agent, a nucleic acid identifier ligand (biotinylated nucleic acid), and a labeled decoder ligand as instantly claimed.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the above described array compositions as suggested generically in Pinkel et al. with generic species of analyte detection sandwich entities as also suggested and motivated in Pinkel et al. of the type as reviewed in the art as in Matthews et al. (1988) as described above to result in the practice of the above

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listed instant invention as claimed in the above listed claims with a reasonable expectation of success for species of protein bioactive agents with nucleic acid identifier binding ligands.

No Claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 30, 2004

Ardin H. Marschel 10/30/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER